

Application No. 10/825,522
Amendment dated June 10, 2008
Reply to Office Action of March 10, 2008

REMARKS

Applicant amended claims 1-10 and added new claims 11-15 to further define Applicant's claimed invention. Support for the amendment to independent claim 1 can be found at least on page 4, lines 6-8, page 15, lines 9-15 of the specification, and in FIGS. 3A and 5. Support for the amendment to independent claim 6 can be found at least on page 9, lines 9-13 of the specification, and in FIGS. 5 and 9. Support for new claims 11-15 can be found at least on page 9, lines 9-13 of the specification, and in FIGS. 3A, 5, and 9. No new matter has been added.

In the Office Action, the Examiner rejected claims 1-10 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,485,517 ("517 patent"). Applicant respectfully traverses the double-patenting rejection.

The present application is a divisional application of U.S. Application No. 10/246,931 ("931 application"), which is a divisional application from Application No. 09/566,272 ("272 application"), now the '517 patent. In reply to a Restriction Requirement dated December 4, 2001 in the '272 application, Applicant cancelled claims drawn to a method for inserting spinal fusion implants across a disc space. A copy of the December 2001 Restriction Requirement is attached hereto as Exhibit A. In reply to a Restriction Requirement dated October 24, 2003 in the '931 application, Applicant cancelled claims drawn to the method for inserting spinal fusion implants across a disc space. A copy of the October 2003 Restriction Requirement is attached hereto as Exhibit B. In the present application, Applicant is pursuing the subject matter of the claims of the '931 application that were cancelled in response to the October 2003 Restriction Requirement.

Moreover, Applicant submits that the process for using the product as claimed in the present application can be practiced with another materially different product than the products claimed in the '517 patent and the '931 application. By way of example, in the '517 patent independent claim 1 recites an implant including at least the attribute of "opposite portions being angled toward each other along at least a portion of said length." Independent claim 70 recites an implant including at least the attribute of "opposite portions having at least one screw hole passing therethrough adapted to transmit a screw passing

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from said trailing end through an interior of said implant and into the adjacent vertebral body." Independent claim 86 recites an implant including at least the attribute of a "trailing end being anatomically contoured to correspond to the natural contour of at least a portion of the anterior aspect of the vertebral bodies."

In the '931 application, independent claims 87 and 88 each recite an implant including the attribute of "a characteristic formed on at least said exterior surface of said trailing end of said implant...adapted to indicate, during insertion of said Implant into the spine, a rotational orientation of said upper and lower arcuate portions relative to the adjacent vertebral bodies into which said Implant is adapted to be inserted" with the starting point of the thread of the implant "being indexed such that insertion of said implant in said initial insertion orientation positions said upper and lower arcuate portions toward the adjacent vertebral bodies upon a predetermined number" of rotations of the implant.

At least these attributes of the implants claimed in the '517 patent and in the '931 application are not required in the methods claimed in the present application. Applicant agrees with the Examiner's statements in the above-identified Restriction Requirements that "[b]ecause these inventions are distinct...and have acquired a separate status in the art as shown by their divergent subject matter and required searches, restriction for examination purposes as indicated is proper." (Exhibit A, page 3, lines 5-7; and Exhibit B, page 2, lines 15-17.) Applicant respectfully requests the Examiner to withdraw the double patenting rejection as being improper.

The Examiner rejected claims 1-3, 5-8, and 10 under 35 U.S.C. § 102(b) as being clearly anticipated by U.S. Patent No. 5,055,104 to Ray ("Ray"). Applicant amended independent claim 1 to recite forming first and second bores across the disc space by removing arc shaped portions from each of the vertebral bodies adjacent the disc space, at least a portion of the second bore overlapping the first bore, the first and second bores each having a mid-longitudinal axis, "the mid-longitudinal axes of the first and second bores being at an angle to one another." Ray teaches "positioning a pair of" fusion cages "in parallel threaded bores between adjacent vertebrae." (col. 3, lines 24-25). Ray does not

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disclose or suggest forming two bores across the disc space such that the mid-longitudinal axes of the two bores are at an angle to one another as recited in independent claim 1.

Applicant amended independent claim 6 to recite a "first implant having opposite arcuate portions adapted for placement toward and at least in part within the adjacent vertebral bodies, a medial side, and a lateral side, the medial side having a portion extending from one of the opposite arcuate portions to another of the opposite arcuate portions, the portion of the medial side being concave in a direction facing away from the lateral side," the "concave portion of the medial side of the first implant being oriented such that the concave portion will substantially lie on an arc defined by the radius of the second cylindrical hole adjacent thereto." FIGS. 1 and 2 of Ray show that each of implants 10 and 20 has a medial side that is convex in direction facing away from the lateral side of the implant. FIG. 5 of Ray shows an implant with a flat medial side. FIGS. 6 and 7 of Ray show a C-shaped implant not having a medial side.

The Examiner rejected claims 4 and 9 under 35 U.S.C. § 103(a) as being unpatentable over Ray. Applicant respectfully traverses the rejection. Ray discloses a method of implanting threaded fusion cages "that allows their threads to overlap, while assuring that the axes of the implanted cages are parallel." (col. 2, lines 60-62). Ray further teaches that the two implanted cages are "side-by-side with their axes parallel" and that the "pairs can be implanted with their parallel axes separated by only about 15 or 16 mm." (col. 3, lines 8-9, 44-46). Ray does not disclose or suggest positioning implants within the first and second bores at an angle toward each other as recited in dependent claims 4 and 10. Applicant submits that it would not be obvious to one of ordinary skill in the art to position the two fusion cages at an angle toward each other at least because Ray expressly teaches away from such a method.

Applicant submits that independent claims 1 and 6 are patentable and that dependent claims 2-5 and 7-10 dependent from one of independent claims 1 and 6, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim. Applicant submits that the Examiner's rejections of claims 1-10 under 35 U.S.C. §§ 102(b) and 103(a) over Ray have been overcome.

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New independent claim 11 recites a method including providing a first implant and a second implant each having a body with "a root diameter defined by opposite arcuate portions adapted for placement toward and at least in part within the adjacent vertebral bodies, a lateral side and a medial side opposite the lateral side connecting the opposite arcuate portions, each of the opposite arcuate portions, medial side, and lateral side having a portion of a thread extending therefrom, the medial side being concave in a direction facing away from the lateral side;" and threading the first and second implants into the first and second of the overlapping cylindrical holes, respectively, "at least a portion of the root diameter of the second implant being received within the root diameter of the first implant." No such method is disclosed or suggested by Ray. Applicant submits that new claim 11, and claims 12-15 dependent therefrom, are patentable over Ray.

In view of the foregoing remarks, it is respectfully submitted that the claims, as amended, are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

MARTIN & FERRARO, LLP

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Hartville, Ohio 44632
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EXHIBIT A



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/566,272	05/05/2000	Gary K. Michelson, M.D.	101.0069-00000	2588

22882 7590 12/04/2001

MARTIN & FERRARO
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SUITE 300
CHANTILLY, VA 201511101

EXAMINER

WILLSE, DAVID H

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

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DEC 10 2001

MARTIN & FERRARO LLP

JUN 10 2008

DN

Office Action Summary

Application No.

09/566,272

Applicant(s)

MICHELSON, GARY K.

Examiner

Dave Willse

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2000.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-100 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received. -
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-85, drawn to a pair of interbody spinal fusion implants, classified in class 623, subclass 17.11.
- II. Claims 86-90, drawn to an interbody spinal fusion implant, classified in class 623, subclass 17.11.
- III. Claims 91-100, drawn to a method for inserting spinal fusion implants across a disc space, classified in class 623, subclass 17.11.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the limitation "wherein the area between said leading end and trailing end along a substantial portion of said medial side is substantially open" (claim 86, last three lines) and the "characteristic" as set forth in the last lines of claims 87 and 88 are not requirements of the broadest combination claims. The subcombination has separate utility such as an independent, single piece implant.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case, the process as claimed can be used with another materially different product such as a pair of implants *not* having opening(s) for permitting bone ingrowth, and the product as claimed can be used in a materially different process such as implanting the two devices in a spaced apart relationship so as to improve the stability of the fusion.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent subject matter and required searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I:	Figures 3A and 4A;
Species II:	Figure 3B;
Species III:	Figure 3C;
Species IV:	Figure 4B;
Species V:	Figures 5-8;
Species VI:	other disclosed pair or set of implants.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species (MPEP § 809.02(a)).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is (703) 308-2903 and who is generally available Monday through Thursday during most of each day. The supervisor, Corrine McDermott, can be reached at (703) 308-2111. The receptionist's phone number is (703) 308-0858, and the main FAX numbers are (703) 305-3591, 3590.

dhw: D. Willse
November 27, 2001

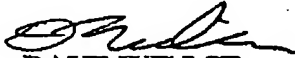

DAVE WILLSE
PRIMARY EXAMINER
ART UNIT 3738

EXHIBIT B



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/246,931	09/19/2002	Gary K. Michelson	101.0069-01000	2450

22882 7390 10/24/2003
MARTIN & FERRARO, LLP
1557 LAKE O'PINES STREET, NE
HARTVILLE, OH 44632

EXAMINER

WILLSE, DAVID H

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 10/24/2003

5

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JUN 10 2008

Office Action Summary	Application No.	Applicant(s)	
	10/246,931	MICHELSON, GARY K.	
	Examiner	Art Unit	
	Dave Willse	3738	

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- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 86-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
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- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 86-100 are subject to restriction and/or election requirement.

Application Papers

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Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 86-90, drawn to an interbody spinal fusion implant or apparatus, classified in class 623, subclass 17.11.
- II. Claims 91-100, drawn to a method for inserting spinal fusion implants across a disc space, classified in class 623, subclass 17.11.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process as claimed can be used with another materially different product such as implants *not* having opening(s) for permitting bone ingrowth, and the product as claimed can be used in a materially different process such as well known methods for inserting *single* implants or spaced apart implants.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent subject matter and required searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

This application contains claims directed to the following patentably distinct species of the claimed invention:

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Page 3

Species I:	Figures 3A and 4A;
Species II:	Figure 3B;
Species III:	Figure 3C;
Species IV:	Figure 4B;
Species V:	Figures 5-8;
Species VI:	other disclosed pair or set of implants.

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Page 4

Art Unit: 3738

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dhw: D. Willse
October 23, 2003


DAVE WILLSE
PRIMARY EXAMINER
ART UNIT 3738